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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/021,407 | 12/12/2001 | Edward A. Rhad | END-795 | 3685 |

27777 7590 07/10/2003

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EXAMINER

FOREMAN, JONATHAN M

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3736

DATE MAILED: 07/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

EC

Office Action Summary

Application No.

10/021,407

Applicant(s)

RHAD ET AL.

Examiner

Jonathan ML Foreman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 - 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 - 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No.

3,605,750 to Sheridan et al.

2. In reference to claims 5 and 6, Sheridan et al. discloses applicant's claimed invention (Figures 15 and 16) including a thermoplastic (Col. 3, lines 65 – 70) elongated substantially tubular member having a distal end, a proximal end, a longitudinal axis therebetween (Col. 4, lines 42 – 45), and a port (98) on the needle; a distal tip attached to the distal end of the tubular member having a hollow cavity (64) filled with a material (82) which will leave an artifact (Col. 6, lines 10 – 27).

Sheridan et al. discloses that the tubular member can be any medico-surgical tube including those used with syringes (i.e. a needle).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5 – 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,534,778 to Loos et al. in view of U.S. Patent No. 5,782,764 to Werne.

In reference to claims 5 and 8, Loos et al. discloses a biopsy device (Figure 8) compatible for use with a MRI machine comprising: a substantially tubular needle having a distal end, a proximal end, and a longitudinal axis therebetween (Col. 6, lines 24 – 25), a port on the needle for receiving a

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tissue sample; and a sharpened distal tip attached to the distal end of the needle (Col. 6, lines 25 – 30). The distal tip is has a hollow cavity and the hollow cavity is shown to be partially filled with a material (93) that will leave an artifact under MRI (Figure 8; Col. 6, lines 25 – 33). It can be seen in the cross-section of the needle shown in Figure 8 that the material (93) is in fact located within the distal tip of the hollow needle (85). This cross-sectional figure of the needle shows that the phrase “hollow needle” (Col. 6, line 26) makes reference to the fact that there is no solid material forming the needle between the outer surface and the surface defining the interior lumen, not that there is an interior lumen for the thin rod (87) to pass through. Loos et al. discloses gadolinium to be a suitable material (Col. 6, lines 36 – 39). However, Loos et al. fails to disclose the needle being formed of a non-metallic material. Werne teaches a biopsy device compatible for use with a MRI machine wherein the needle is formed of a non-metallic material (Col. 8, lines 36 - 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle as disclosed by Loos et al. to be formed of a non-metallic material as taught by Werne so as to not distort or degrade the images obtained with the MRI machine.

In reference to claims 6 and 7, Werne discloses the needle comprising a glass fiber reinforced polymer resin (Col. 8, lines 36 – 65), but fails to disclose the needle comprising a thermoplastic. However it would have been obvious to one having ordinary skill in the art to form the needle of any material that meets the desired function, such as a thermoplastic. The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Response to Arguments

5. Applicant's arguments with respect to claims 5 - 8 have been considered but are moot in view of the new ground(s) of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF
July 2, 2003



MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
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